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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,738	02/28/2002	Kevin S. Weadock	15314 (ETH-1636)	8872

7590 03/16/2010  
Scully, Scott, Murphy & Presser  
400 Garden City Plaza  
Garden City, NY 11530

EXAMINER
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EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3773

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03/16/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/085,738	<b>Applicant(s)</b> WEADOCK ET AL.	
	<b>Examiner</b> Darwin P. Erez	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-11 and 14-47 is/are pending in the application.
- 4a) Of the above claim(s) 3,10,11,16-28 and 34-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-9,14,15,29-33 and 38-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. This Office action is in response to the applicant's communication filed on 12/18/09.

#### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1,4-9,14,15,29-33 and 38-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,117,147 to Simpson et al. in view of US 6,743,243 to Roy et al. and in further view of US 6,726,923 to Iyer et al. (and as evidenced by US 6,176,864 to Chapman).

(claim 1) Simpson discloses a device for creating an end-to-side anastomosis (col. 1, lines 6-9), including a body 14 comprising an inner surface defining a through opening configured to receive a portion of graft vessel 10 (see Fig. 5B); the body having a proximal flat surface configured to appose an outer surface of the target vessel 22 (see Fig. 5B); a distal surface distanced from the outer surface of the target vessel 22 (the opposite end of the body), the through opening extending from the proximal surface to the distal surface (see Fig. 5B); and a securing means 34 for securing the outer surface of the target vessel to the proximal surface of the cylindrical body (see Fig. 5B).

Simpson is silent with regards to the body being formed from a resorbable sponge, or to the body being substantially cylindrical with a uniform diameter, or with a securing means disposed on the inner surface of the body for securing to the graft vessel.

However, the use of resorbable sponges is well known in the anastomosis art. Iyer discloses that it is known to form anastomosis support devices from biocompatible, biodegradable, resorbable matrix material such as collagen, which can be made into a sponge material (col. 8, ll. 56-65). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the device of Simpson from collagen because collagen can be used to imbibe a drug in order to provide

medicaments to the anastomosis site, while also allowing the device to be resorbed into the body.

With regards to the use of cylindrical anastomosis support devices, Iyer also discloses an anastomosis support having a straight side surface providing a uniform diameter (see Fig. 7). Therefore, it would have been obvious to one of ordinary skill in the art at time the invention was made to further modify the device of Simpson to have a uniform diameter since such configuration is well known in the art, as disclosed by Iyer, and since it has been held that changing the shape of a working part involves only routine skill in the art. *In re Dailey*; 357 F.2d 669, 149 USPQ 47 (CCPA 1966). Note that US 6,176,864 to Chapman is another art that discloses a support device 70 used in end to side anastomosis, wherein the device is cylindrical with a uniform shape. Though Chapman discloses a different type of connection to the target vessel, the device itself is fully capable of being secured to the outer surface of the vessel since the body has sufficient thickness for applying adhesives.

With regards to the a securing means disposed on the inner surface of the body for securing to the graft vessel, it is noted that Roy discloses a similar device for creating an end to side anastomosis between vessels, the device comprising an extravascular body (shown in Fig. 1) having an inner surface and outer surface, and adhesives on the inner surfaces of the first tubular member **1** and the inner surface of the second tubular member **2** (col. 5, lines 23-26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Simpson to use the adhesives of Roy as it will provide additional securing

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means between the graft vessel, the target vessel and the body. Note that the use of activated adhesives are well known in the art, as taught by Simpson in col. 2, lines 7-8, which would allow the surgeon the maneuver the body into position before the adhesives attach the graft and target vessels.

(claims 4-5, 7-9) Roy discloses the inner surface of the tubular element **2** is provided with adhesive to seal the element onto the vessel. Therefore, the modified device of Simpson would have the same arrangement. The adhesive would also be disposed in the sponge material after being modified by the Iyer reference. Simpson already discloses an adhesive for securing the body to the outer surface of the target vessel.

(claim 6) Simpson is silent with regards to the use of a balloon catheter. However, the use of a balloon catheter during anastomotic surgery is well known in the art. For example, Roy discloses a balloon catheter that is used to attach the tubular element to the blood vessel (col. 6, ll. 7-9). Therefore, it would have been obvious to use a balloon catheter with the device of Simpson because it would help stabilize the graft vessel against the target vessel.

(claims 14 and 15) The modified device of Simpson will be formed with the collagen disclosed by Iyer, which includes a medicament, such as an anastomosis modulating agent (see abstract). Simpson also discloses his device (prior to being modified to a resorbable sponge) being able to deliver medication.

(claim 29) The modified device of Simpson, as recited in claim 1, discloses all the steps of claim 29, including providing a body with a cylindrical, uniform shape, first and second securing means, and forming an anastomosis.

(claims 30, 31 and 38-41) The modified device of Simpson would have the graft vessel attached to the body opening via adhesives and the target vessel is attached to the portion of the outer surface of the body via adhesives; the target vessel has a hole and the body is positioned over the hole as a "cap"; wherein a balloon catheter is used (as recited in the rejection to claim 6 above).

(claim 32 and 33) Simpson is silent with regards to when the hole is formed. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to either have the hole formed subsequent to attaching the portion of the target vessel to the body or prior to attaching the portion of the target vessel to the body since a hole must necessarily be formed in order to create an end-to-side anastomosis and that the step of when the hole is formed would be a mere design choice.

(claims 42 and 43) The blood flows intraluminally through the graft and target vessels.

(claims 44-46) Simpson discloses the axis of the body to be perpendicular to the outer surface of the target vessel, but is silent with regards to opening forming an acute angle relative to the outer surface of the target vessel (or the axis of the body forming an acute angle with the outer surface of the target vessel). However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to

modify the device of Simpson to have the recited shape since it has been held that changing the shape of a working part involves only routine skill in the art. *In re Dailey*; 357 F.2d 669, 149 USPQ 47 (CCPA 1966). Furthermore, the applicant has not provided any criticality for the recited shape since the applicant also provides a shape for the body having an acute angle relative to the outer surface of the target vessel. Therefore, the shape of the elongated body would be a mere obvious design choice to one of ordinary skill in the art.

(claims 46-47) The modification to have the body of Simpson to have a uniform cylindrical body would provide a body having a consistent thickness.

### ***Response to Arguments***

6. Applicant's arguments with respect to claims 1, 4-9, 14, 15, 29-33 and 38-47 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any



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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezó whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezó/  
Primary Examiner, Art Unit 3773